The Impact of GFSI and Other Drivers on Environmental Monitoring

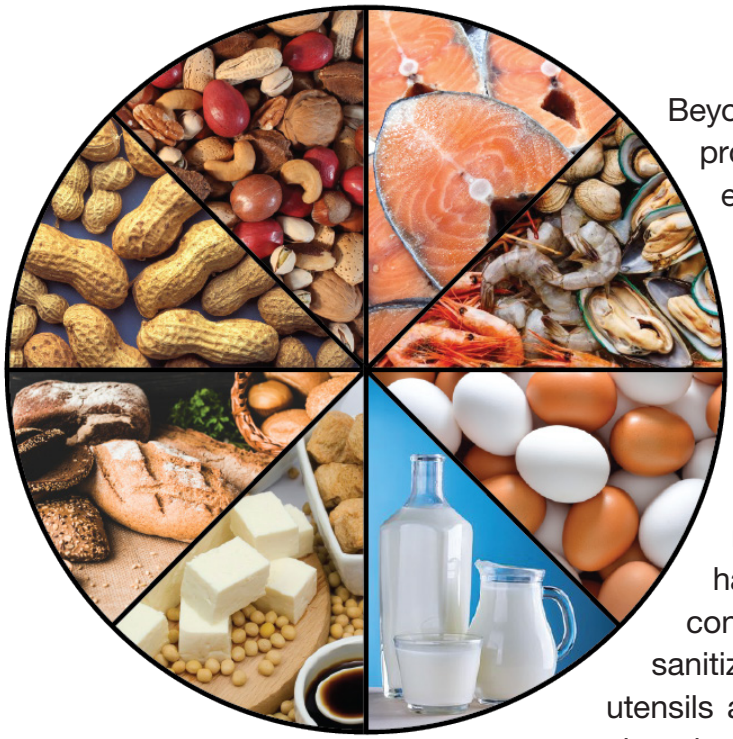
Environmental monitoring programs have served as essential verification programs in a company's HACCP plan for a long time. Driven by regulation, private standards and brand protection, environmental monitoring programs (EMP) and the critical role these programs play in food safety are the subject of increasing attention in the last few years. This article will address these drivers, with focus on how private standards such as the Global Food Safety Initiative (GFSI) are changing industry's approach to environmental monitoring.

Regulatory Drivers

As regulation evolves in the United States from HACCP to risk-based preventive controls, the final FDA Food Safety Modernization Act (FSMA) rules include new requirements pertaining to EMP programs, and broaden the range of processes and products that are affected by these new requirements.

Specifically the Current Good Manufacturing Practice, Hazard Analysis And Risk-Based Preventive Controls for Human Food (PCHF Rule) states that covered facilities must conduct activities that include the following, as appropriate to the facility, the food and the nature of the preventive control:

1. Calibration of process monitoring instruments and verification instruments (or checking them for accuracy)
2. Product testing for a pathogen (or appropriate indicator organism or other hazard)
3. Environmental monitoring for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples[1]. **Hence environmental monitoring is expected when producing RTE foods with risk of a pathogenic hazard.**



Beyond pathogens, testing your environment and/or products for other hazards is also advantageous to ensure your food safety system remains in control. Allergens remain the leading cause for recalls in the United States in 2017[2]. Thus, having tight allergen management control is critical. For example, as required under the FSMA PCHF Rule, your hazard analysis identifies food safety hazards requiring a preventive control. If those hazards involve the U.S. regulated "Big 8" allergens (peanuts, tree nuts, milk, eggs, fish, shellfish, soy, and wheat) you may have placed an allergen and a sanitation preventive control in place to ensure you effectively cleaned and sanitized your food contact surfaces, equipment and utensils after running a unique allergen and before running a product that does not contain that unique allergen. How do you know if you have achieved a true clean? How do you know if the allergen containing protein did not disseminate more broadly in your production environment and risk an allergen cross-contact event? Use of allergen and sanitation testing within a holistic EMP program to confirm cleaning efficacy can help you answer these questions with confidence.

It is important to note that allergen regulation varies by country. Food Standards Australia New Zealand (FSANZ), the agency that regulates most food in Australia and New Zealand (countries who have received systems recognition by FDA)[3], requires certain allergens to be labeled, however they vary slightly from the U.S. list; they are peanuts, tree nuts, milk, eggs, fish, shellfish, soy, wheat and add sesame seeds and lupin. Hence it is important to ensure you are correctly labeling your product and to manage your programs accordingly to meet regulations both for the country of manufacture and for the country of export/intended distribution.

Based on the above, it is no surprise then that FDA is paying closer attention to EMP programs. More importantly, it is paying attention to the corrective actions put in place upon finding issues. Jenny Scott, senior adviser, FDA Center for Food Safety and Applied Nutrition, Office of Food Safety, stated that FDA "will be asking our inspectors to pay attention to the environmental monitoring data at a facility but [pay] particular attention to the corrective actions taken…[4]". The agency is more concerned that facilities are sampling the right areas, have results that look good and/or are reasonable in light of their plans, and have good CGMPs (Current Good Manufacturing Practices) in place. Then there may be no point for the agency to take any samples in a facility. "Any positive findings can be mitigated by the right corrective actions. We don't expect facilities to never find a positive—we hope they will occasionally find positives—but the focus will be on the corrective actions taken and making sure there is ultimately no problem with their product[5]." Hence, having a robust EMP program setting forth sampling areas, sample sizes, frequencies and corrective actions is critical to a successful EMP program.

Equally important to remember, as touched on above, successful food safety programs and EMP programs hinge on an accurate hazard analysis that thoroughly assesses the risk inherent to your product, processes, suppliers, facility and nature of your food safety programs. If challenged with this task, resources such as state extension services, universities, contractors and consultants can also provide guidance on how to conduct a proper risk assessment including which organisms may be advisable to monitor in your EMP programs.

It is important to remain mindful that FSMA is a US-centric regulation, impacting those producing facilities that manufacture, process, pack or hold food in the U.S. or in foreign countries for U.S. consumption; GFSI's requirements are industry-adopted and global in application. We will explore GFSI's requirements as it relates to this topic in more detail below.

GFSI and its Certification Programme Owners

What may be the principal driver in the evolution of environmental monitoring is GFSI's requirements and that of its Certification Programme Owners (CPO's, formerly known as Scheme Owners) such as SQF, BRC, IFS and FSSC 22000.

GFSI requires documented environmental monitoring programs be in place when certain conditions are present. Before delving into the specific requirements, it will be helpful to understand the premise and purpose of GFSI. With a vision of *Safe Food For Consumers Everywhere*, GFSI was formed in 2000 by food industry leaders from various industry sectors to drive reduction in three key areas: 1) food safety risks, 2) audit duplication and 3) audit costs, while simultaneously increasing trust throughout the supply chain[6]. GFSI is managed by the international trade association, The Consumer Goods Forum, a network of the world's largest global consumer goods retailers, and their respective manufacturers and suppliers[7].

GFSI CPO's

- SQF
- BRC
- IFS
- FSSC 22000
- Primus GFS
- Global G.A.P.
- Canada GAP
- Global Aquaculture Alliance
- Global Red Meat Standard

GFSI requires what many would describe as a slightly broader set of EMP requirements that a food facility/processor must adopt than is required by FSMA. Specifically, the standard is as follows:

> The standard shall require that a risk-based environmental monitoring program be in place which includes all high-care and high-risk areas[8].

SQF goes beyond the GFSI Benchmark requirement and requires in edition 8 (effective January 2018) that all human and pet food facilities have a risk-based environmental monitoring program in place for all manufacturing processes—not just high risk/high care facilities as required in edition 7.2[9].

Why expand on the GFSI Benchmark requirement?

When SQF conducted research on its existing environmental monitoring requirement in edition 7.2 it revealed that approximately 50% of its sites did not qualify for the high-risk facility designation, hence receiving an N/A on the audit. It was also seeing a lack of consistent definition as to what sites truly should have been considered high risk/high care. The inconsistency was at all stakeholder levels (certification bodies, facilities, auditors and even CPOs).

Recognizing its importance, SQF wanted to single out EMP as its own requirement under its food safety system element. The requirement isn't mandatory, but SQF does require a facility to conduct a risk assessment to determine the extent that it is required to control for environmental pathogens[10]. If it is determined that an EMP program is necessary then the full set of the new edition 8 requirements for environment monitoring should be followed, set forth below:

2.4.8 ***Environmental Monitoring***

2.4.8.1 *A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.*

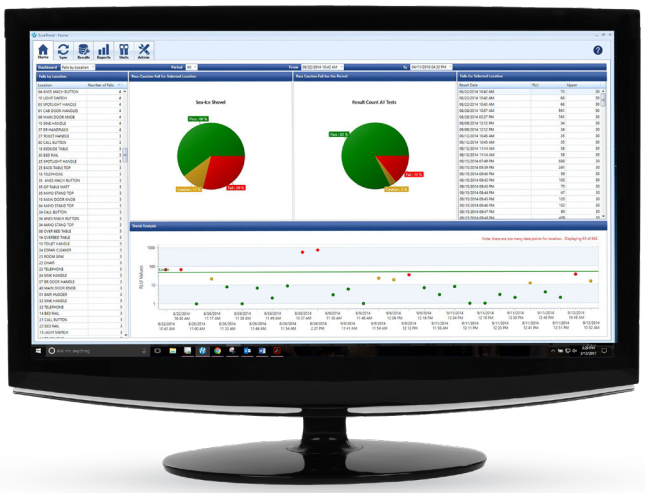
2.4.8.2 *The responsibility and methods for the environmental monitoring program shall be documented and implemented.*

2.4.8.3 *An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.*

2.4.8.4 *Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.*

Other Factors Driving Change to EMP Programs

Other dynamics impacting EMP programs involve data analytics and the need for program optimization for regulatory and brand protection.



Hygiena's Suretrend Data Analysis Software captures sanitation monitoring trends.

The sheer volume of data produced in an average EMP program is overwhelming. The ability to harness and harmonize information from environmental monitoring data is critical. Turning data into actionable information and intelligence (e.g. usable dashboards), utilizing meaningful analytics to provide trending and visibility to all facilities is more important than ever before to drive continuous improvement, corrective action and change what is needed to stay a step ahead of the new risk landscape we now find ourselves in. One of the biggest risks a company has is having the data under its nose but not "seeing" that it was trending off the rails until it was too late. Industry must be able to leverage technology to mitigate this type of risk by turning mountains of data into usable, actionable information. EMP data is an excellent place to start.

- Is your EMP program fully optimized, proactive and truly risk-based?
- Is your sample size and testing frequency statistically significant to find positives?
- Are your personnel properly trained in swabbing methodologies and regulatory testing requirements?
- What tests is your company using?
- Are you leveraging the power of big data by trending your results so as to be alerted to usual trends before they result in more significant problems?
- What third party laboratories are you partnered with to get a different view/perspective?

These are all timely and relevant questions being asked by inspectors, auditors, and industry to ensure your programs are updated for new regulations, private standards and brand protection requirements. Thus, these may be good questions to add to your own internal checklist as you undertake an assessment of the health of your EMP program.

Conclusion

GFSI's concentration on risk-based environmental monitoring programs and FSMA's focus on prevention are increasing the importance of environmental monitoring and testing as the results provides corporate and facility food safety personnel with a signal that corrective action may be needed to prevent a potential future contamination event. This is why it is so important to ensure your company's EMP plans are updated post-FSMA and to meet new GFSI benchmark and CPO requirements such as SQF's enhanced requirements effective in January 2018. It is important to caution that building your program to minimum regulatory requirements will not afford your company much of a safety net if you have a bad day—regulatory compliance is the floor; programs built to the standard of brand protection will fair far better and provide that safety net when there is a potential for positives that could trigger a larger market action.

Ultimately what is most important is that your plan reflects a program that is written to find positives, to reward personnel for finding rather than not to find them, to protect the valuable brand reputation of your company and that of your customers and to preserve consumer health and safety.

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Hygiena delivers rapid microbial detection, monitoring, and identification solutions to a wide range of industries, including food and beverage, healthcare, hospitality, pharmaceuticals, and personal care. Utilizing advanced technologies and patented designs, Hygiena provides industry-leading ATP monitoring systems, PCR-based pathogen detection and characterization systems, allergen tests, environmental collection devices, and more. Hygiena is committed to the mission of providing customers with high-quality innovative technologies that are easy-to-use and reliable, backed by excellent customer service and support. Headquartered in in Camarillo, California with offices in Wilmington, Delaware, Canada, Mexico, the United Kingdom and China, and over 80 distributors in more than 100 countries worldwide, Hygiena products span the globe.

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